K030581

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Name of Firm:	Blackstone Medical, Inc. 90 Brookdale Drive Springfield, MA 01104
510(k) Contact:	Dean E. Ciporkin Director of Regulatory Affairs and QA
Trade Name:	Blackstone™ Spinal Fixation System Spinal Fixation System Lateral Offset
Common Name:	Rod and screw spinal instrumentation
Device Product Code & Classification:	**MNH** – 888.3070 – Spondylolisthesis Spinal Fixation Device System **KWQ** - 888.3060 - Spinal Intervertebral Body Fixation Orthosis **MNI** – 888.3070 – Pedicle Screw Spinal System **KWP** - 888.3050 - Spinal Interlaminal Fixation Orthosis

Substantially Equivalent Devices:

Blackstone™ Spinal Fixation System (K994217)
Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws (K020674)
Blackstone™ Spinal Fixation System 4.5mm Mono-Axial Screws (K013558)
Blackstone™ Spinal Fixation System 2nd Gen. Cross-Connector (K003735)
Blackstone™ Spinal Fixation System Modified Multi-Axial Screws (K023498)
Blackstone™ Spinal Fixation System Hooks (K013885)
Blackstone™ Spinal Fixation System Spacers (K022399)
Blackstone™ Spinal Fixation System Staple & Washer (K022605)

Device Description:

The Blackstone™ Spinal Fixation System is comprised of titanium alloy (6AL-4V ELI, per ASTM F136) devices in a variety of non-sterile, single use components. This system allows a surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws and hooks to the non-cervical spine.

The lateral offset addition will function as an offset rod connector. There are clinical applications in which a surgeon will need to have the inter-operative ability to attach rods in an offset manner when building a construct.

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Intended Use / Indications for Use:

The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
b) Who are receiving fusion using autogenous bone graft only;
c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and
d) Who are having the device removed after the development of a solid fusion mass.

The Blackstone Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

a) Degenerative spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudarthrosis).

The Blackstone Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

The Blackstone Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:

a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies);
b) spondylolistheses;
c) spinal stenosis;
d) spinal deformities (i.e., scoliosis, kyphosis, lordosis);
e) tumor;
f) pseudoarthrosis;
g) previous failed fusion; and
h) trauma (i.e., fracture or dislocation).

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BASIS OF SUBSTANTIAL EQUIVALENCE:

The Blackstone™ Lateral Offset by its very nature is substantially equivalent to the Synthes, Interpore Cross and Surgical Dynamics devices, which have been cleared by FDA for certain indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Mr. Dean E. Ciporkin
Director, Regulatory Affairs and Quality Assurance
Blackstone Medical, Inc.
90 Brookdale Drive
Springfield, Massachusetts 01104

Re: K030581
Device name: Blackstone™ Spinal Fixation System – Lateral Offset
Regulatory Name(s): 888.3060 Spinal intervertebral body fixation orthosis
888.3070 Pedicle screw spinal system
888.3050 Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP, KWQ
Dated: May 28, 2003
Received: May 30, 2003

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K030581

Device Name: **ORIA Spinal Clip System**

Indications for Use:

When used as a nonpedicle, noncervical posterior system, the ORIA Spinal Clip System is indicated for: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); (2) spondylolisthesis; (3) fracture; (4) spinal stenosis; (5) deformities (i.e., scoliosis, kyphosis, lordosis), (5) tumor, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

ORIA Spinal Clip System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) at L5-S1 joint; (2) who are receiving fusions using autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of solid fusion mass.

When used as a pedicle screw system in the non-cervical spine of skeletally mature patients, the ORIA Spinal Clip System is indicated for immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative spondylolisthesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and (7) failed previous fusion (pseudarthrosis).

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030581

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

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